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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,675	10/01/2003	Harald Kropshofer	21412	8495

151 7590 03/10/2006

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,675	KROPSHOFER ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: KROPSHOFER *et al*

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   i. Claims 1-6 and 22-31, drawn in part to a peptide of selected from the group consisting of SEQ ID Nos: 1-13, and 21, a pharmaceutical composition, and a diagnostic marker comprising said peptide, classified in class 530, subclass 300, for example. If applicant elects this group for prosecution on the merits, applicant is further required to select a single sequence from SEQ ID Nos: 1-13, and 21 for examination on the merits. This selection should not be construed as an election of species.

   II. Claim 7-9, drawn to an antibody reactive with the antigenic peptide of group I, classified in class 530, subclass 350. If applicant elects this group for prosecution on the merits, applicant is further required to select a single sequence from SEQ ID Nos: 1-13, and 21 for which the antibody reacts for examination on the merits. This selection should not be construed as an election of species.

   III. Claims 10-21 drawn to a nucleic acid molecule encoding a peptide or polypeptide of group I, host cells comprising the said nucleic acid, vectors comprising said nucleic acid, and a method of producing the the antigenic peptide of group I, classified in class 536, subclass 23.1, for example. If applicant elects this group for prosecution on the merits, applicant is

further required to select a single sequence from SEQ ID Nos: 1-13, and 21 which the instant nucleic acid encodes for examination on the merits. This selection should not be construed as an election of species.

IV. Claims 32-40, drawn to a method of treating cancer comprising stimulating the production of protective antibodies or immune positive CD4+ cells comprising the administration of the peptides of group I, classified in class 514, subclass 2, for example. If applicant elects this group for prosecution on the merits, applicant is further required to select a single sequence from SEQ ID Nos: 1-13, and 21 to administer for the treatment of cancer for examination on the merits. This selection should not be construed as an election of species.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-III are patentably distinct products.

a. The polypeptide of group I and polynucleotide of group III are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. A polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group III, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity

chromatography. For these reasons, the inventions of groups I and III are patentably distinct.

Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and III together.

b. The polypeptide of group I and the antibody of group II are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant

and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group II are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group II is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group I is a molecule which contains regions to which an antibody may bind, whereas the antibody of group II is defined in terms of its binding specificity to a small structure within sequence of SEQ ID No: 1-13, or 21. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group I and group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group II. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group II are not coextensive, e.g., antibodies may be

characterized in the technical literature prior to discovery of or sequence of their binding target.

c. The polynucleotide of group III and the antibody of group II are patentably distinct for the following reasons. The antibody of group II includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group III will not encode an antibody of group II, and the antibody of group II cannot be encoded by a polynucleotide of group III. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group III and group II would impose a serious search burden since a search of the polynucleotide of group III is would not be used to determine the patentability of an antibody of group II, and vice-versa.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to catalyze an enzymatic reaction as opposed to its use in a method of treating cancer.

Searching the inventions of Groups I and IV together would impose serious search burden. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treating cancer using the polypeptide are not coextensive. Group I encompasses molecules which are claimed in terms of sequence identity to SEQ ID Nos: 1-13, or 21, which are not solely required for the search of Group IV. In contrast, the search for group IV would require a text search for the method of treating cancer in addition to a search for a sequence of SEQ ID No 1-13, or 21. Prior art which teaches a polypeptide to SEQ ID No 1-13 or 21 would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID No 1-13 or 21. Moreover, even if the polypeptide product were known, the method of treatment which uses the product may be novel and unobvious in view of the preamble or active steps.

5. Inventions II, III and IV are unrelated because the products of group II, III is not used or otherwise involved in the process of group IV.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
March 6, 2006

CHRISTOPHER YAEN
PATENT EXAMINER